PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

Date of mailing (day month year)
25 January 2001 (25.01.01)

International application No.
PCT/GB00/02641

International filing date (day month year)
15 June 2000 (15.06.00)

PETATS-UNIS D AMERIQUE
In its capacity as elected Office

Applicant's or agent's file reference
P006424WOCTH

Priority date (day month year)
17 June 1999 (17.06.99)

Applicant

DONALDSON, lain, Alasdair et al

in the demand filed with the International Preliminary Examining Authority on:	
22 November 2000 (22.11.00)	
in a notice effecting later election filed with the International Bureau on:	
The election X was	
was not	
made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland acs imme No. 14124-1740 14-35

Authorized officer

S. Mafla

Tempor and two collins is stated as



(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P006424W0CTH		of Transmittal of International Search Report 220) as well as, where applicable, item 5 below.		
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)		
PCT/GB 00/02641	15/06/2000	17/06/1999		
Applicant				
DANISCO A/S				
This International Search Report has bee according to Article 18. A copy is being to	en prepared by this International Searching Aut ansmitted to the International Bureau.	thority and is transmitted to the applicant		
This International Search Report consists				
It is also accompanied by	y a copy of each prior art document cited in this	s report.		
Basis of the report				
 With regard to the language, the language in which it was filed, ur 	e international search was carried out on the ba nless otherwise indicated under this item.	asis of the international application in the		
the international search v Authority (Rule 23.1(b)).	was carried out on the basis of a translation of	the international application furnished to this		
b. With regard to any nucleotide a was carried out on the basis of the		nternational application, the international search		
	onal application in written form.			
filed together with the int	filed together with the international application in computer readable form.			
furnished subsequently to this Authority in written form.				
T furnished subsequently to this Authority in computer readble form.				
the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.				
the statement that the infurnished	formation recorded in computer readable form	is identical to the written sequence listing has been		
2. Certain claims were for	und unsearchable (See Box I).			
3. Unity of invention is la	cking (see Box II).			
4. With regard to the title ,				
the text is approved as s	submitted by the applicant.			
the text has been estable	shed by this Authority to read as follows:			
RICE SUCROSE SYNTHASE	PROMOTER			
5. With regard to the abstract,				
the text has been establi	submitted by the applicant. ished, according to Rule 38.2(b), by this Autho he date of mailing of this international search re	rity as it appears in Box III. The applicant may eport, submit comments to this Authority.		
6. The figure of the drawings to be pul	plished with the abstract is Figure No.			
as suggested by the app	plicant.	X None of the figures.		
because the applicant fa	illed to suggest a figure.			
because this figure bette	er characterizes the invention.			

Inti ional Application No PCT/GB 00/02641

A. CLASSI IPC 7	FICATION OF SUBJECT MATTER C12N15/54 C12N9/10 C12N15/	82 A01H5/00		
According to	o international Patent Classification (IPC) or to both national classific	cation and IPC		
	SEARCHED			
IPC 7				
	tion searched other than minimum documentation to the extent that at a base consulted during the international search (name of data base)			
	ternal, WPI Data, PAJ, BIOSIS, CHEM			
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT			
Category °	Citation of document, with indication, where appropriate, of the re	elevant passages	Relevant to claim No.	
X	HUANG JU-WEI ET AL: "Complete s of three rice sucrose synthase i and differential regulation of t expression." BIOSCIENCE BIOTECHNOLOGY AND BIO vol. 60, no. 2, 1996, pages 233-XP002158594 ISSN: 0916-8451 the whole document	sogenes heir CHEMISTRY,	1-7, 10-12, 15-19, 23,26	
X	WANG M-B ET AL: "A COMPLETE SEQ THE RICE SUCROSE SYNTHASE-1 RSS1 PLANT MOLECULAR BIOLOGY, vol. 19, no. 5, 1992, pages 881- XP002158595 ISSN: 0167-4412 the whole document	GENE"	6,7,10, 11, 15-19,26	
X Furt	her documents are listed in the continuation of box C.	Patent family members are listed	in annex.	
*T later document published after the international filing date or pnontly date and not in conflict with the application but cited to understand the principle or theory underlying the			the application but	
considered to be of particular relevance "E" earlier document but published on or after the international filing date "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone				
which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "O" document referring to an oral disclosure, use, exhibition or other means "O" document is combined with one or more other such document, such combination being obvious to a person skilled in the art.				
later t	ent published prior to the international filing date but han the priority date claimed	*&* document member of the same patent		
	actual completion of the international search 26 January 2001	Date of mailing of the international sea	arcn report	
	mailing address of the ISA	Authorized officer		
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 Oderwald, H				

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Inti ional Application No PCT/GB 00/02641

		PCT/GB 00/02641
C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	DATABASE EMGSS3 'Online! EMBL Heidelberg, Germany; AC/ID AQ272200, 4 November 1998 (1998-11-04) WING R A AND DEAN R A: "A BAC end sequencing framework to sequence the rice genome" XP002158597 abstract	1,2,5,7, 10,11, 13, 15-19, 23,26
X	WO 98 10062 A (MONSANTO CO) 12 March 1998 (1998–03–12) the whole document	6,7,10, 11, 15-22,26
X	"Original TA cloning kits, pCR2.1 vector" INVITROGEN CATALOGUE, 1997, page 7 XP002158596 the whole document	24

Information on patent family members

Intc...ional Application No PCT/GB 00/02641

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9810062 A	12-03-1998	AU 4173497 A	26-03-1998

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 28 December 2000 (28.12.2000)

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English

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17 June 1999 (17.06.1999) GI

- (71) Applicant (for all designated States except US): DANISCO A/S [DK/DK]; Langebrogade 1, P.O. Box 17, DK-1001 Copenhagen K (DK).
- (72) Inventors; and
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- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

- With international search report.
- (88) Date of publication of the international search report: 31 May 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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- (51) International Patent Classification7: 9/10, 15/82, A01H 5/00
- C12N 15/54,
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- (22) International Filing Date: 15 June 2000 (15.06.2000)
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9914210.1

17 June 1999 (17.06.1999)

- (71) Applicant (for all designated States except US): DANISCO A/S [DK/DK]; Langebrogade 1, P.O. Box 17, DK-1001 Copenhagen K (DK).
- (72) Inventors; and
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- (74) Agents: HARDING, Charles, Thomas et al.; D Young & Co., 21 New Fetter Lane, London EC4A 1DA (GB).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK. DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

Without international search report and to be republished upon receipt of that report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



(54) Title: PROMOTER

(57) Abstract: A promoter is described. The promoter comprises a nucleotide sequence corresponding to that shown as SEQ ID No. 1 or a variant, homologue or derivative thereof.



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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or	agent's file reference		
P006424WOCTH FOR F		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. International fil		International filing date (day/month	h/year) Priority date (day/month/year)
PCT/GB00/	02641	15/06/2000	17/06/1999
International PC12N15/54	atent Classification (IPC) or n	ational classification and IPC	
DANISCO A	VS		
1. This inte	rnational preliminary examansmitted to the applicant	nination report has been prepared according to Article 36.	by this International Preliminary Examining Authority
2. This REF	PORT consists of a total of	f 8 sheets, including this cover sl	heet.
beer	n amended and are the ba	ed by ANNEXES, i.e. sheets of th sis for this report and/or sheets c 07 of the Administrative Instruction	e description, claims and/or drawings which have ontaining rectifications made before this Authority ons under the PCT).
These ar	nnexes consist of a total of	f sheets.	
_		ating to the following items:	
	Basis of the report Priority		
)) ([]		oninion with regard to nevelty inv	rentive step and industrial applicability
	Lack of unity of invention		entive step and industrial applicability
V E	Reasoned statement u		novelty, inventive step or industrial applicability;
VI =	Certain documents citi		
VII 🖺	Certain defects in the in	nternational application	
VIII E	Certain observations or	n the international application	
Date of submiss	sion of the demand	Date of c	completion of this report
22/11/2000		12.09.20	001
preliminary exam	ng address of the internationa mining authority:	Authorize	ed officer
<i>o</i>))) ⊳.	ropean Patent Office 80298 Munich I. +49 89 2399 - 0: Tx: 523656	Mueller	, F

Telephone No. +49 89 2399 7722

Fax: +49 89 2399 - 4465

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02641

1.	Basi	s of	the	report
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1.	the an	receiving Office in	ments of the international application (Replacement sheets which have been furnished to response to an invitation under Article 14 are referred to in this report as "originally filed" o this report since they do not contain amendments (Rules 70.16 and 70.17)):				
	1-1	08	as originally filed				
	Cla	ims, No.:					
	1-2	6	as originally filed				
	Dra	wings, sheets:					
	1/2	7-27/27	as originally filed				
2.	Wit lang	With regard to the language , all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.					
	The	se elements were a	available or furnished to this Authority in the following language: , which is:				
		the language of a	translation furnished for the purposes of the international search (under Rule 23.1(b)).				
		the language of pu	blication of the international application (under Rule 48.3(b)).				
		the language of a f 55.2 and/or 55.3).	translation furnished for the purposes of international preliminary examination (under Rule				
3.	With	n regard to any nuc rnational preliminar	leotide and/or amino acid sequence disclosed in the international application, the yexamination was carried out on the basis of the sequence listing:				
		contained in the in	ternational application in written form.				
		filed together with	the international application in computer readable form.				
		furnished subsequ	ently to this Authority in written form.				
		furnished subsequently to this Authority in computer readable form.					
		The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.					
		The statement that listing has been fur	the information recorded in computer readable form is identical to the written sequence mished.				
4.	The	amendments have	resulted in the cancellation of:				
		the description,	pages:				
		the claims,	Nos.:				

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02641

	the drawings,	sheets:
5. 🗆		n established as if (some of) the amendments had not been made, since they have been yond the disclosure as filed (Rule 70.2(c)):
	(Any replacement sl report.)	neet containing such amendments must be referred to under item 1 and annexed to this

- 6. Additional observations, if necessary:
- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N) Yes: Claims 3,4,8-14,23,25

No: Claims 1,2,5,6,7,15-22,2426

Inventive step (IS) Yes: Claims 3,4,8-14,23,25

No: Claims 1,2,5,6,7,15-22,24,26

Industrial applicability (IA) Yes: Claims 1-26

No: Claims

2. Citations and explanations see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted: see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made: see separate sheet

Re Item I

Basis of the opinion

Sequence listings filed, 4 pages, Seq IDs.: 1-6, with the letter of 11.09.2000, are filed after the filling date of the application and do not form part of the description and will not be annexed to this communication/report (Rule 13ter(f) PCT).

Re Item V

Reasoned statement under Article 35 (2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: WO 98 10062 A (MONSANTO CO) 12 March 1998 (1998-03-12)
- D2: 'Original TA cloning kits, pCR2.1 vector' INVITROGEN CATALOGUE, 1997, page 7
- D3: DATABASE EMGSS3 [Online] EMBL Heidelberg, Germany; AC/ID AQ272200, 4 November 1998 (1998-11-04) WING R A AND DEAN R A: 'A BAC end sequencing framework to sequence the rice genome'
- The subject-matter of independent claim 1 is not novel (Article 33 (2) PCT).
 D3 describes a sequence which is partially complementary to Seq Id 1 of the present application. The sequence of D3 has a homology of 90% between nucleotides 1-112 of the claimed Seq Id 1.

The same holds true for independent claim 2 and dependent claim 5.

2. The subject-matter of independent claims 6 and 26 is not novel (Article 33 (2) PCT).

D1 describes the rice (which is considered as genus Oryza) glutelin-1 promoter (p.4,l.3-14) which is used for expressing foreign mammalian genes in the endosperm (p.23,l.20-22, figures 4 and 5 and p.24, l.26-33 and claims). All technical features of claims 6 and 26 are disclosed in D1, the requirements of novelty are thus not fulfilled.

- 2.1 The same holds true for thereon dependent claim 7.
 D1 describes the glutelin-1 promoter which is operably linked to the sequences of the light and heavy chains of BR96 (see figures 4 and 5 and e.g. p.9, l. 10-12).
 The BR96 sequences are considered to represent a NOI.
- 3. The subject-matter of independent claims 15,16,17 and 18 is not novel (Article 33 (2) PCT).

D1 describes a construct which is suitable for the expression of mammalian genes in endosperm by using a glutelin-1 promoter expression vector. Thus novelly of claim 15 can not be acknowledged.

The same holds true for independent claims 16 and 17.

Furthermore D1 refers to a transformed host cell (maize) containing a rice-glutelin promoter expression construct (see claims 8-10). The requirements of novelty for claim 18 are therefore not fulfilled (Article 33 (2) PCT).

The same holds true for thereon dependent claim 19.

4. The subject-matter of independent claims 20 and 22 is not novel (Article 33 (2) PCT).

D1 describes a method for preparing foreign gene products (p.20,l.23-p.21,l.26) from transformed maize plants (p.18,l.26- p.20,l.23) by using an glutelin-1 promoter expression construct (see item also 2). All technical features of independent claims 20 and 22 are therefore disclosed in D1.

The same holds true for thereon dependent claim 21.

- 5. The subject-matter of independent claim 24 is not novel (Article 33 (2) PCT). D2 refers to a commercially available vector construct which is used in the present application (see e.g. on page 78, I.18-PCR2.1). Novelty can therefore not be acknowledged.
- 6. The subject-matter of claims 3,4,8-14,23 and 25 is novel (Article 33 (2) PCT). The promoter sequence presented as Seq Id 1 in the present application is novel. Furthermore the use of seq id 2 (an intron sequence) and seq id 5 (an exon

sequence) within the claimed promoter expression construct used for recombinant expression in plant cells is novel.

6.1 The subject-matter of claims 3,4,8-14,23 and 25 is inventive (Article 33 (3) PCT). The closest prior art is considered to be D1. D1 describes an glutelin-promoter containing expression vector which is suitable for the expression of mammalian genes in maize (see item 2 and 4).

The problem to be solved by the present application may therefore be regarded as to provide a different promoter which allows endosperm expression in plants. A solution therefore is provided in the present application by the use of RSus3 promoter sequence of rice (seq Id 1). In addition it was found that the combination of Seq Id 2 (an intron sequences) and Seq Id 5 (an exon sequence) with that Seq Id 1 is suitable for modulating (to elevate) the expression levels of a NOI (see p.11,I.7-12).

As there is no indication in the prior art to use the RSus 3 promoter alone or in combination with the specific intron and exon sequences for allowing expression of mammalian genes in plants, an inventive step can be acknowledged (Article 33 (3) PCT).

7. The further cited X-documents in the International Serch Report; Huang et al., describing genomic sequences of the rice sucrose synthaseand which is silent over promoter sequences and vector constructs for recombiant expression and Wang et al., describing the rice RSs1 gene; are not considered to be relevant in respect to novelty or inventive step.

Re Item VII

Certain defects in the international application

1. Pages 16/27,17/27 and 18/27 (figures 16a-16f) of the drawings are only partially readable and therefore do not fulfil the requirements of Rule 11 (6)(c) PCT. When amendments to the drawings are made greatest care should be taken not contravening the requirements of Article 34 (2)(b) PCT.

- 2. The vague and imprecise statement "...without departing from the scope and spirit.." in the description on page 105, lines 9-16, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also PCT Guidelines, C-III, 4.3).
- 3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in document D1 is not mentioned in the description, nor is this document identified therein.
- 4. The application should be self-contained. Therefore the term "incorporated by reference" e.g. on page 30, line 29 and on page 105, line 8 does not fulfil the requirements of the PCT-Guidelines C-II,4.17.
- 5. The reference to non-published patent applications (e.g. on p.29, I.16) should be changed to published application numbers throughout the application (PCT Guidelines,C-II.4.17).

Re Item VIII

Certain observations on the international application

- Claims 1,2,8,9,13 are not clear (Article 6 PCT).
 The terms "variant, homologue, fragment or derivative thereof" renders the subject-matter for which protection is sought unclear. The technical features of the claimed nucleotide sequences therefore should be defined by the definitions out of the description on page 25, line 9- page 26, I.22.
- 2. The terms "comprising" and "having" have the same meaning and therefore renders the set of claims 1 and 2 unclear (Article 6 PCT). It seems that the term "having" should be replaced by "consisting".
- 3. It is not clear from the wording of claims 1,2,6,23 and 26 if the promoter is an isolated promoter. Thus the requirements of Article 6 PCT are not fulfilled.
- 4. Claims 10 and 11 are not clear (Article 6 PCT).

The promoter comprising sequences should be identified by sequences identification numbers.

- The term "comprising the invention" does not describe any technical features and 5. therefore render claims 16-18 unclear (Article 6 PCT).
- 6. Claim 23 is not clear (Article 6 PCT). No technical features for isolating the promoter sequence from the deposited microorganism are provided.
- 7. Claim 24 is not clear (Article 6 PCT). The technical features of the plasmids are fully undefined.
- 8. Claim 26 does not meet the requirements of Article 6 PCT. The term "substantially" render the technical features of the promoter unclear.